ARPA ORDER NUMBER: D824

CONTRACT NUMBER: N00014-97-C-0133

EFFECTIVE DATE OF CONTRACT: 4/10/97

EXPIRATION DATE OF CONTRACT: 4/10/99

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FINAL TECHNICAL REPORT

ARPA ORDER NO.: D824 **PROGRAM CODE NO.:** 5V10

PROGRAM ELEMENT NO.: 63570E

CONTRACTOR: GUIDED THERAPY SYSTEMS, INC. **CONTRACT AMOUNT:** $749,900

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PRINCIPAL INVESTIGATOR: MICHAEL H. SLAYTON, Ph.D.

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SHORT TITLE OF WORK: "2-D ULTRASOUND SCANNING PROBES FOR 3-D MEDICAL DIAGNOSTIC IMAGING"

INTRODUCTION

Three dimensional (3-D) medical diagnostic imaging appears to be one of the major technical advancements of this decade. It is being pursued vigorously by the industry and is technologically feasible. However, cost versus performance issues are currently extremely sensitive and holding back commercialization of a number of 3-D technical concepts. Our technical approach will allow commercialization of a thoroughly needed 2-dimensional acquisition system (2-D probes and controller modules), which are uniformly recognized as a critical part of a 3-dimensional ultrasound imaging system.

Any commercially viable system has an architecture driven primarily by cost and performance issues. 2-D phased and linear arrays would certainly meet the performance requirements should the major technological obstacles be surmounted. A large number of research papers were devoted to resolve such issues (e.g. [1],[2],[3],[4]), however the cost and considerations for such arrays, with thousands of elements to interconnect and drive, have not been resolved to date.

In this project we have shown the feasibility of achieving a balance between cost and performance for 2-D probes by the means of utilizing electronic arrays and integrated control modules, with a mechanically driven, compact 2-D imaging probe (see Fig 1).

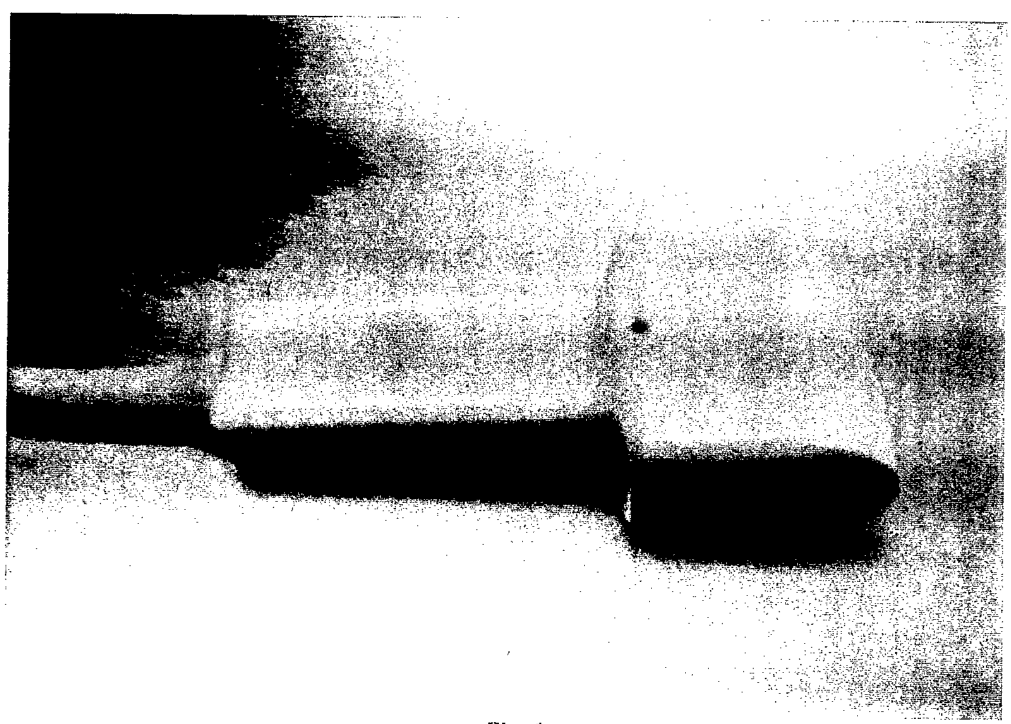


Fig. 1

TECHNICAL ACHIEVEMENTS

The following technical goals and new technologies were planned and achieved during the project:

(1) Development of optimized, wide bandwidth linear array and phased array modules for the 2-D probes.

(2) Development of small, hand-held, robust, high quality 2-D probes incorporating the above described array modules.

(3) Modular form of design for the 2-D probes with acoustically compatible materials for high quality imaging in 3-D.

(4) Cost effective modular design with the state-of-the-art flexible PCB (FPCB) with small pitch micro-motors with high gauge coaxial cables.

(5) Compact electronic controller module as a part of 2-D/3-D acquisition system for 3-D imaging.

According to the established detailed work plan (see Table 1) the specification for the 2-D acquisition system was developed and optimized for transducer array modules in the frequency range of 5 MHz to 9 MHz were developed, fabricated and tested. (Task 1, 2, Table 1)

A test system with high precision X, Y, Z displacement capabilities and a flexible water tank set-up was developed and constructed. Such system allowed us, among other things, to perform an acoustic test of the material samples as well as array modules. The system also provided means for controlling, synchronizing, and recording 2-D scan planes to form 3-dimensional images and accommodate a variety of targets, including tissue phantoms (Task 4, Table 1, Fig. 2).

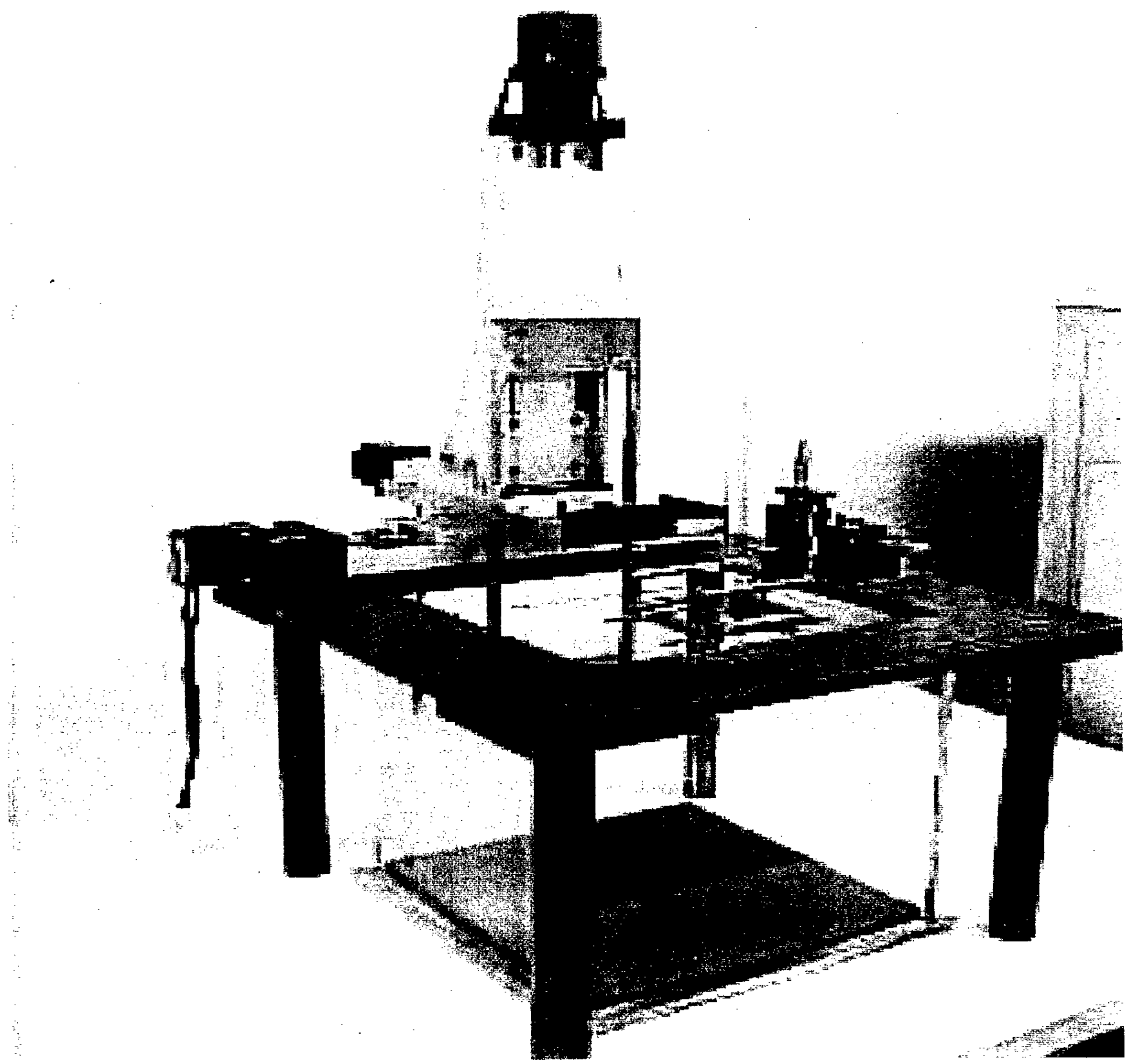


Fig. 2

To fulfill the technical goals 3 and 4 we have developed and fabricated prototypes of "wet and interconnect" modules, with additional multi-element coaxial cables, and integrated them with a variety of transducer array modules fabricated previously (Task 3, 5, 8, Table 1).

An extensive reliability testing included 30 days of continuous "burn in", which constituted an uninterrupted 24 hour a day mechanical functioning test. Acoustic liquid temperature variations were measured and analyzed. All the parts of the probe, including FPCB's were subjected to the durability test at the rate of 8 sweeps per second at 90° angle for 720 hours. The results of the testing were as follows:

1) No mechanical failures were observed during or after the reliability test.
2) No visible air bubbles and/or acoustic liquid leakage occurred during the test.
3) Temperature elevation did not exceed 7°F over the ambient temperature and stabilized over a short period of time.

We have designed, produced and tested a micro controller based miniature electronic control module (Microchip PIC16C664 based with C-based Firmware) with RS-232 serial port interface utilized to communicate with the probe (Task 6,7, Table 1).

Nine prototypes were produced with a variety of center frequency arrays (5 MHz, 7.5 MHz, 9 MHz) (Task 9,10, Table 1). The probes (Fig. 1,3,4,5) were tested and utilized for 2-D and 3-D imaging system developed under DARPA sponsored contract #N00014-96-2-0004 (TRP) and produced very good preliminary imaging results (Fig. 6).

ADDITIONAL WORK

GTS has created a software package, combined with the array based 2-D probes, which makes possible the use of the 2-D probes in 3-D imaging applications with other commercial systems, without hardware changes. This additional work makes the 2-D probe development lead to another possible commercial product. The additional work was supported solely by GTS.

SUMMARY

Emerging 3-D medical imaging is almost uniformly addressed by every ultrasound imaging company worldwide has become commercially feasible. Ease of use and cost versus performance issue, however, were holding back the emerging modality as well as number of diagnostic applications.

We have proposed and successfully accomplished, designed, developed, and fabricated a 2-D acquisition system (2-D probes and controller modules, see Specification attached), which are cost effective, self contained, and allow the use of a wide variety of commercial systems available today.

Compared to the number of other approaches that vary from mechanically displaced single element or annular arrays, to transducers with embedded electromagnetic based registration system (e.g. [5], [6]), this approach with 2 dimensional acquisition system is a critical part of three dimensional ultrasound imaging.

As a result of this development, we have been already approached by two technical Consortia requesting to utilize the 2-D probe design, as well as a transducer OEM manufacturer, interested in converting the results of this project into a commercial product.

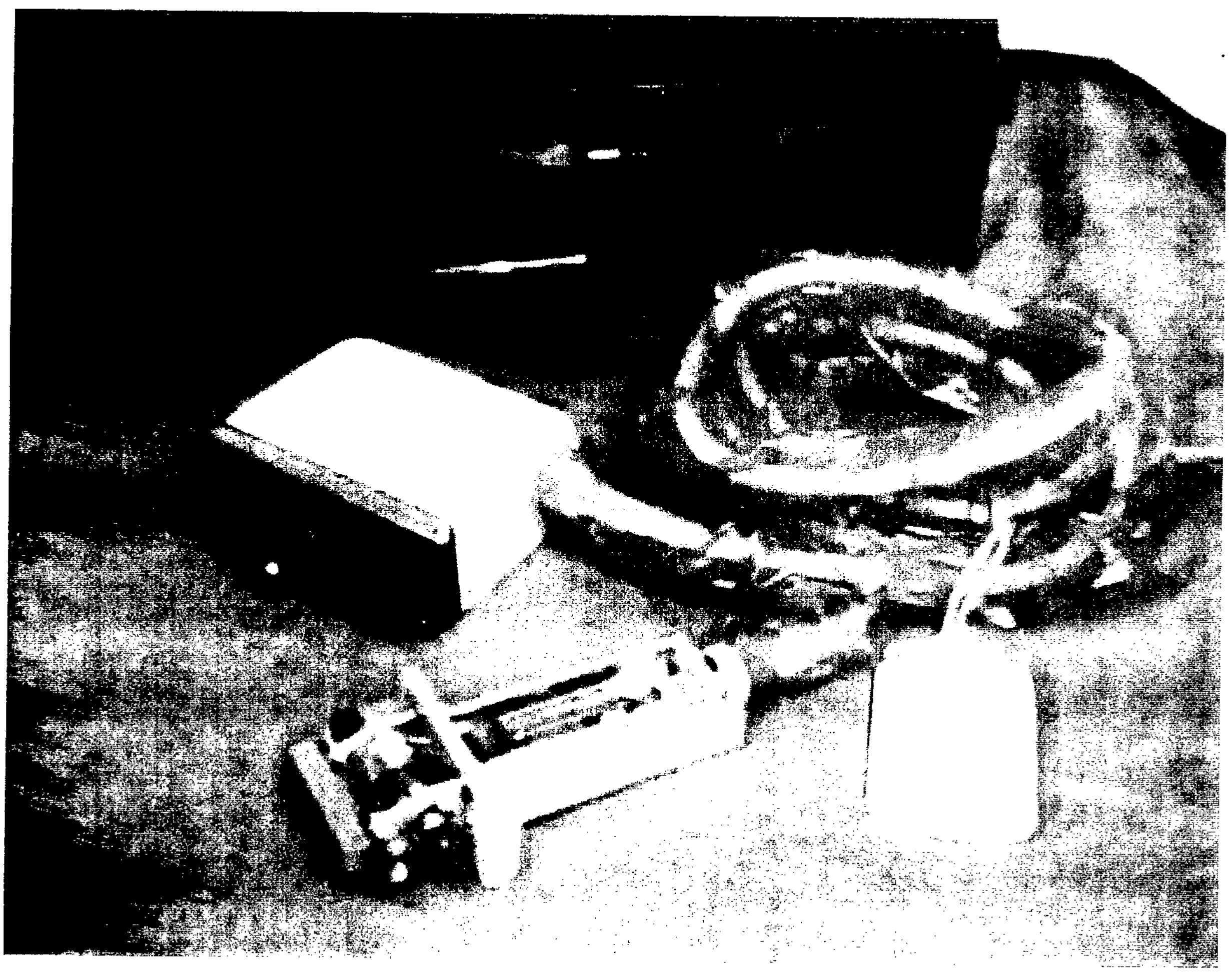


Fig. 3

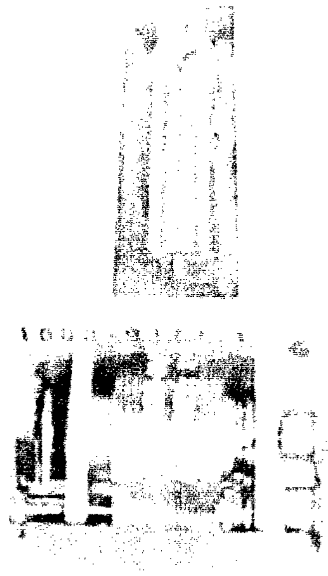


Fig. 4

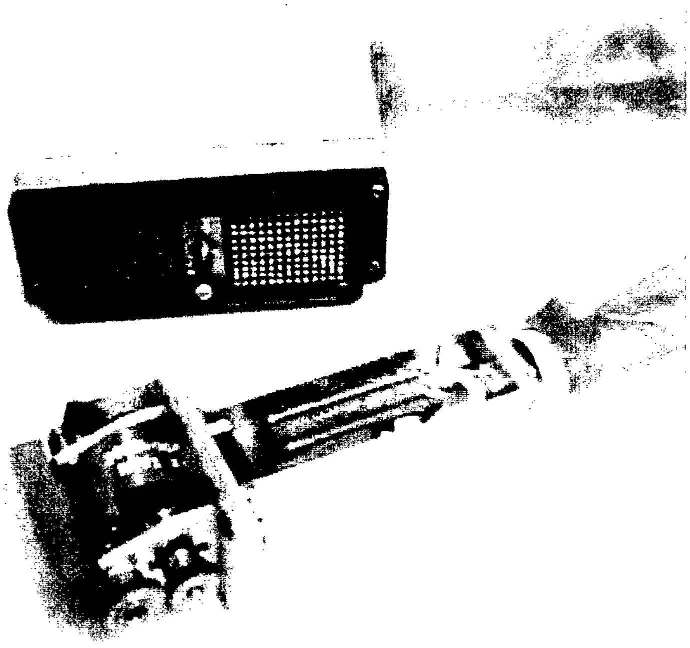
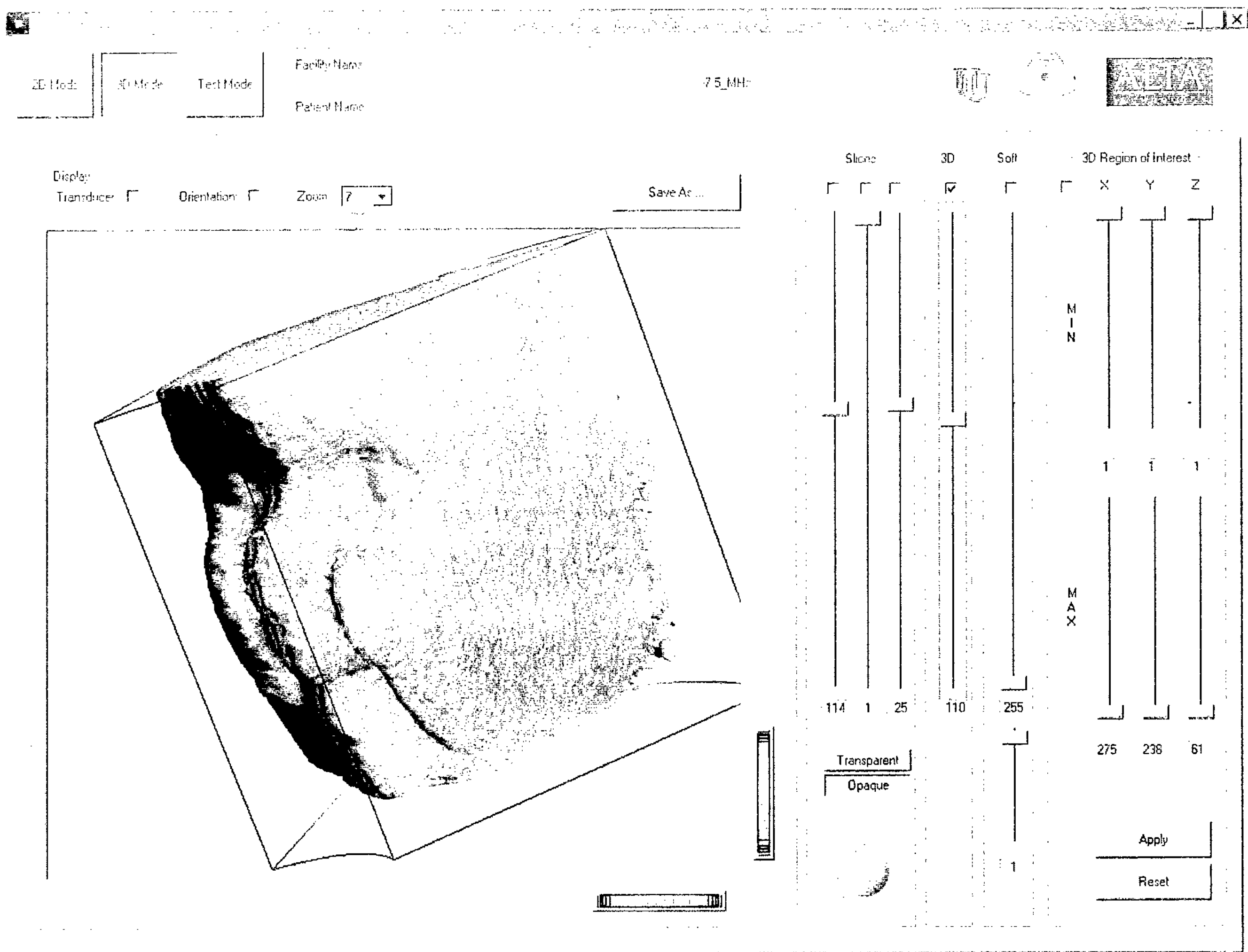


Fig. 5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114
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238
61
Transparent
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Fig. 6

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[4] A. L. Robinson and J. H. Mo, "Applications of Microelectronics and Microfabrication to Ultrasound Imaging Systems", *Proc. 1992 IEEE Ultrasonics Symposium,* pp. 681-691, 1992.

[5] K. A. Spaulding, M. E. Kissner, E. K. Kim, D. H. Pretorius, S. C. Rose, K. Garroosi, T. R. Nelson, "Three-Dimensional Gray Scale Ultrasonographic Imaging of the Celiac Axis", *J. Ultrasound Med.,* vol. 17, pp. 239-248, 1998.

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3-D Probe System Specification

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April 19, 1999

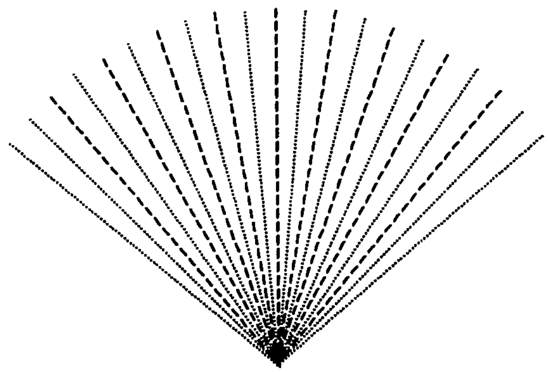

Figure 1. Illustration of 3-D probe's sector scanning. The dotted lines represent individually accessable positions of the stepping motor based system, while the dashed lines represent "frames" in which an image slice is captured. NOTE: during scanning the motor sweeps in a continuous fashion at several kilohertz step rates. Using the notation discussed in the text, the above diagram represents 9 *Frames*, 2 *StepsPerFrame*, and 2 *AccelerationSteps*. The acceleration steps are at the ends of the scan region (for slowing down and speeding up). Typical resolution is 570 frames over 90°.

The Guided Therapy Systems (GTS) three-dimensional (3-D) probe is a mechanical sector-scanning unit that can support a variety of transducer modules, such as linear or phased arrays, curved-linear arrays, and single-element or annular arrays. The probe is microcontroller based, thus can be programmed to work in wide variety of fashions. This document describes typical specifications of the scanning mechanism, the associated hardware, and a simple means of control.

The transducer and scan mechanism are enclosed inside a wet module, and sweeps out a sector as shown in Figure 1. Control of the GTS probe is based on a probe-mounted pushbutton. Normally the module is pointed "straight-ahead" or 0°. When the pushbutton is pressed, the module is swept to the edge of the scan region (including extra distance for acceleration). Then a full sweep is done at the desired settings (angle, number of frames, sweep rate). After the sweep is done, if the probe pushbutton is released, the probe returns to 0°. Otherwise, the probe will continue sweeping until the pushbutton is released. Typically an RS-232 serial port interface is used to communicate with the probe. The communication consists of setting scan parameters,

and getting status information from the probe. However, by changing the probe's firmware, hardwired or other interfaces are possible. An illustration of the system configuration is shown in Figure 2.

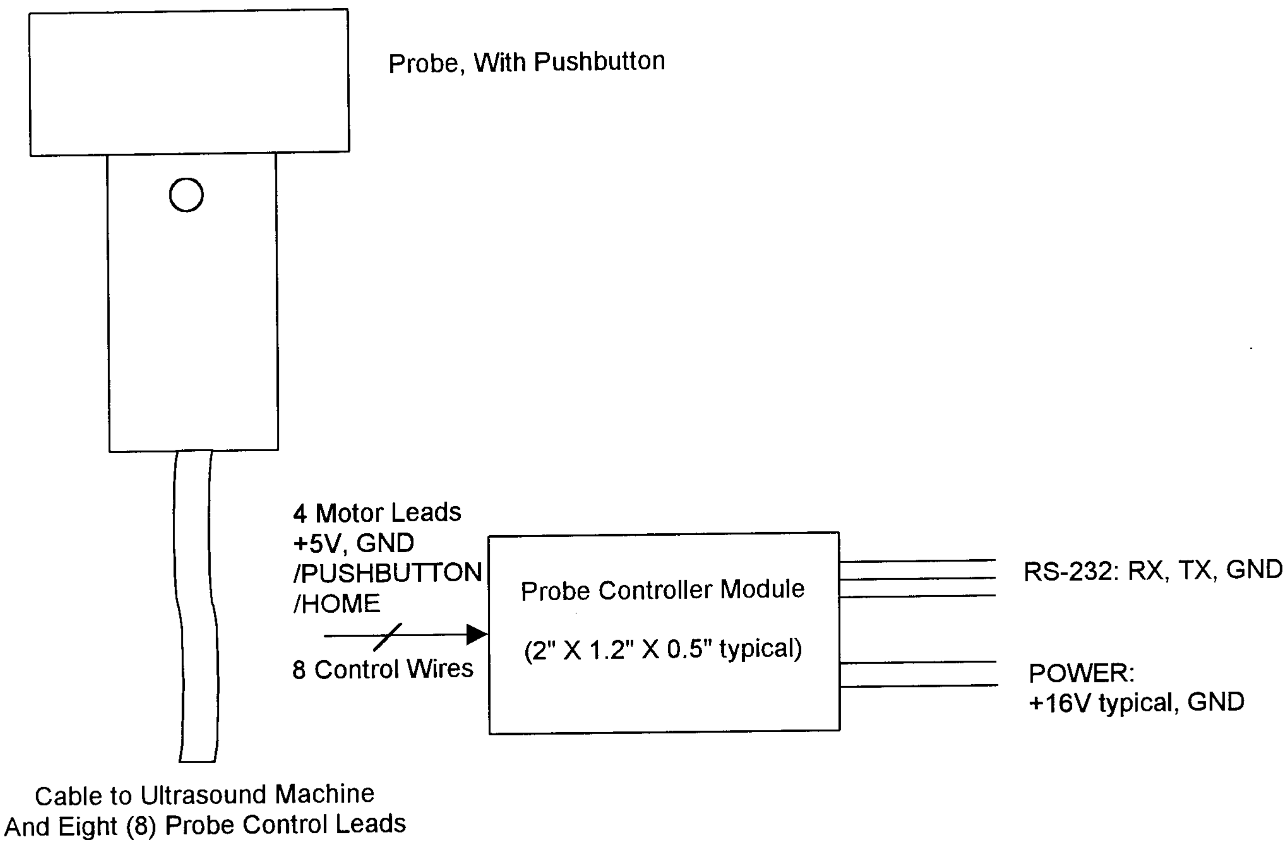

Figure 2. System Configuration, illustrating probe and control electronics module.

The GTS probe has the command set shown in Table 1. Typical specifications are shown in Table 2. Digitial I/O status lines, such as a rising edge strobe could indicate each new frame.

In addition to the low-level system command set, GTS has made a full Microsoft Windows ® 95/98/NT compatible control interface. This high-level graphical user interface allows the user to enter the sweep angle, number of frames, and sweep rate. Also a "frame-grabber" mode captures cropped image regions (sub-areas) on the PC's display. Therefore, 3-D data acquisition can be derived from any Windows-based ultrasound machine without hardware intervention.

Table 1. Low-Level Command Set of GTS 3-D Probe, Firmware V1.0. Fully Customizable.

Command:	Specification (numeric value probe dependent):
Reset	R
Home	H
Frames	F000 to F999
Period	P000 to P999 (0 to 9990 μs/step)
Steps Per Frame	S000 to S999
Acceleration Steps	A000 to A999
Status	Echoes '0' at first frame, 'X' following, 'H' home.
	Also echoes command sent to probe

Table 2. Preliminary Specifications of GTS 3-D Probe.

Parameter:	Specification:
Type	Sector Scanning
Scan Angle	> 90 degree maximum
Module Size, Shape	Variable. Nose-Piece Dependent
Angular Resolution	2280 steps/360 degree or 3/19 degree/step
Sweep Rate	> 10 sweeps/sec
Pushbutton	Momentary, SPST (when ON shorts to GND)
Microcontroller	Microchip PIC16C664, C-based Firmware
Power Supply	16 V, 1/2 Amp typical
Communication Interface	RS-232, 9600 Baud, 8 Data, No Parity, 1 Stop
Home Sensor	Hall-Effect Vane-Interrupter, Open Collector

SCHEDULE OF MAJOR DEVELOPMENT T/

ID		Task Name
1	✓	1. PRELIMINARY SPECIFICATION
2	✓	2. OPTIMIZATION OF TRANSDUCER ARRAYS, FAB AND TEST
3	✓	3. WET MODULE DEVELOPMENT AND FABRICATION AND TEST
4	✓	4. TEST SYSTEM DEVELOPMENT AND FABRICATION
5	✓	5. INTERCONNECT MODULE AND COAXIAL CABLE DESIGN, FAB AND TEST
6	✓	6. CONTROLLER DESIGN
7	✓	7. CONTROLLER FAB AND TEST
8	✓	8. MODULE INTEGRATION
9	✓	9. PRE-PRODUCTION PROTOTYPES FABRICATION
10	✓	10. MODULE AND PROTOTYPES' TESTING

Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	M
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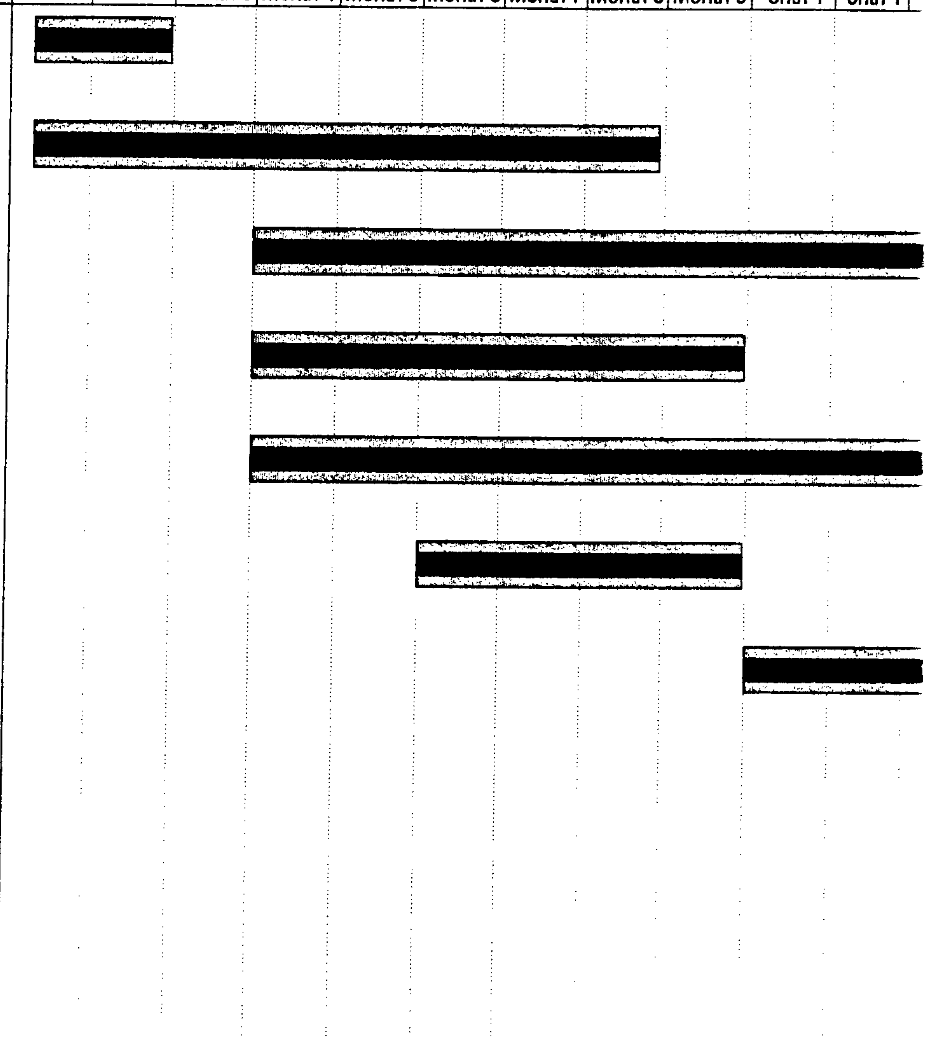

Project: SBIR PHASE II
Date: MAY 10, 1999

Task | Milestone | Rolled Up T
Progress | Summary | Rolled Up S

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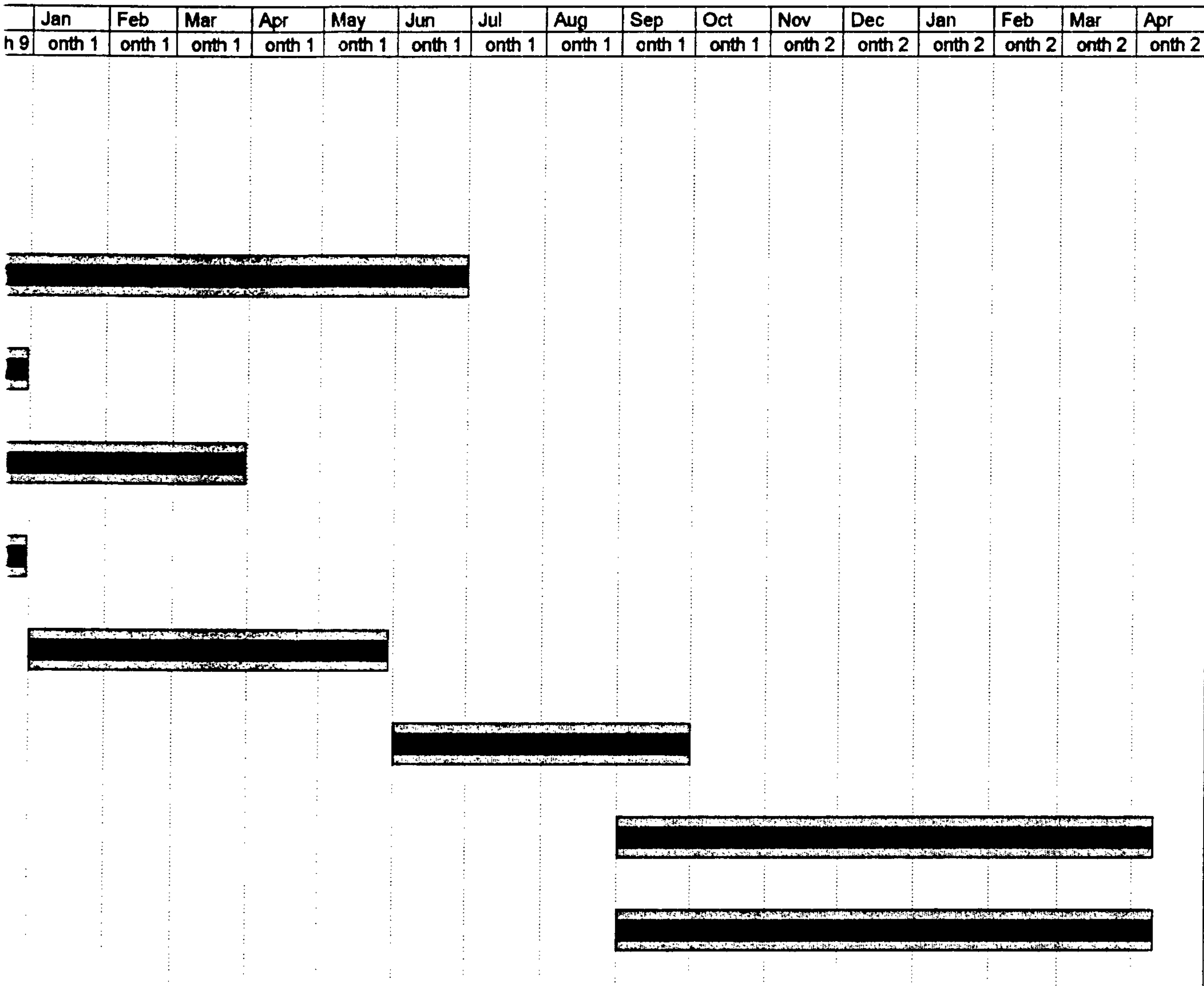

Rolled Up Task	Rolled Up Milestone	External Tasks
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